

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

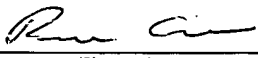
Applicant: David ELSLEY
Title: COMBINED THERAPIES FOR
ATHEROSCLEROSIS
TREATMENT

Appl. No.: 10/089,362

371(c) 1/14/2003
Filing Date:

Examiner: Not Yet Assigned

Art Unit: 1616

| |
|--|
| <p>CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.</p> <p><u>Rene Campos</u> (Printed Name)</p> <p><u></u> (Signature)</p> <p><u>1/24/05</u> (Date of Deposit)</p> |
|--|

TRANSMITTAL

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents for filing in the above-identified application.

1. Second Information Disclosure Statement (3 pgs.);
2. PTO Form SB/08 (1 pg.);
3. Six references as noted on Form SB/08 (C1-C6); and
4. Return postcard.

[X] The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge

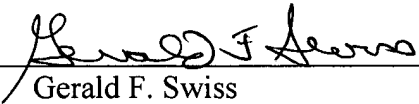
the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

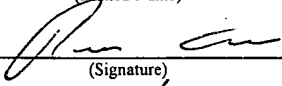
Date 1/24/05

FOLEY & LARDNER LLP
Customer Number: 38706
Telephone: (650) 251-1103
Facsimile: (650) 856-3710

By 
Gerald F. Swiss
Attorney for Applicant
Registration No. 30,113

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David ELSLEY
Title: COMBINED THERAPIES FOR
ATHEROSCLEROSIS
TREATMENT
Appl. No.: 10/089,362
371(c) 1/14/2003
Filing Date:
Examiner: Not Yet Assigned
Art Unit: 1616

| |
|--|
| <p>CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.</p> <p><u>Rene Campos</u> (Printed Name)</p> <p><u></u> (Signature)</p> <p><u>1/24/05</u> (Date of Deposit)</p> |
|--|

SECOND INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to

antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

The relevance of the foreign-language document is described in the present specification. An English translation of the foreign-language document is not readily available. However, the absence of such translation does not relieve the PTO from its duty to consider the submitted foreign language document (37 CFR §1.98 and MPEP §609).

Applicant respectfully requests that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date 1-24-05

By Gerald F. Swiss

FOLEY & LARDNER LLP
Customer Number: 38706
Telephone: (650) 251-1103
Facsimile: (650) 856-3710

Gerald F. Swiss
Attorney for Applicant
Registration No. 30,113

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|--|---|----|---|--------------------------|------------------|
| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: January 24, 2005 (use as many sheets as necessary) | | | | Complete if Known | |
| | | | | Application Number | 10/089,362 |
| | | | | 371(c) Filing Date | 1/14/2003 |
| | | | | First Named Inventor | David Elsley |
| | | | | Group Art Unit | 1616 |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 1 | of | 1 | Attorney Docket Number | 355908-2650 |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|-----------------------|----------------------|-----------------------------------|---|---|---|
| Examiner Initials* | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number | Kind Code ² (if known) | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | | | |
|--------------------------|-----------------------|-------------------------|---------------------|-----------------------------------|--|---|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Documents | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Office ³ | Number ⁴ | Kind Code ⁵ (if known) | | | | |
| | | | | | | | | |
| | | | | | | | | |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
| | C1 | Athyros et al. "Safety and Efficacy of Long-term Statin-Fibrate Combinations in Patients with Refractory Familial Combined Hyperlipidemia" <i>Am. J. Cardiol.</i> 80:608-613 (1997) | |
| | C2 | Tikkanen, Matti J. "Statins: within-group comparisons, statin escape and combination therapy" <i>Current Opinion in Lipidology</i> 7:385-388 (1996) | |
| | C3 | Orekhov et al. "Antiatherosclerotic and antiatherogenic effects of a calcium antagonist plus statin combination: amlodipine and lovastatin" <i>Int. J. Cardiol.</i> (Suppl. 2):S67-S77 (1997) | |
| | C4 | Kostner, K.M. "Aggressive Therapie und Kombinationstherapie bei schweren Hyperlipidämien" <i>WMW-5/6/1999 Themenheft: "HMG-CoA-Reduktase-Hemmer"</i> 1-3 | N |
| | C5 | Feher et al. "Long-term safety of statin-fibrate combination treatment in the management of hypercholesterolaemia in patients with coronary artery disease" <i>Br. Heart J.</i> 74:14-17 (1995) | |
| | C6 | Orekhov et al. "Anti-Atherogenic Effect of Calcium Antagonist Plus Statin Combination" <i>Cardiovascular Drugs and Therapy, Kluwer academic Publishers, Boston, U.S.</i> Vol. 11, no. 2:350 (1997) | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.